

Minimizing Risks of Laparoscopy

This Committee Opinion has been reviewed and approved by the Medico-Legal Committee and the Executive Committee and Council of the Society of Obstetricians and Gynaecologists of Canada.

PRINCIPAL AUTHOR

Titus Owolabi, MD, FRCSC, Toronto, ON

MEDICO-LEGAL COMMITTEE MEMBERS

Titus Owolabi (Chair), MD, FRCSC, Toronto, ON
Douglas Bell, MD, FRCSC, Ottawa, ON
Donald Davis, MD, FRCSC, Medicine Hat, AB
Dan Farine, MD, FRCSC, Toronto, ON
Thomas Guy Hogan, MD, FRCSC, St. John's NF
Ken Milne, MD, FRCSC, Ottawa, ON
Ferdinand Pauls, MD, FRCSC, Winnipeg, MB
Vyta Senikas, MD, FRCSC, Montreal QC
Harold Wiens, MD, FRCSC, Winnipeg, MB

Abstract

Objective: the primary objective of this document is to identify in which patients and under what clinical circumstances complications of laparoscopy are more likely to occur, and to make recommendations based on these factors.

Options: clinical situations where the options include laparoscopy, laparotomy or no surgical intervention.

Evidence: Medline search from 1995 to 1999 for articles related to complications of laparoscopy in numerically significant prospective and retrospective studies, as well as medico-legal data on laparoscopic complications in Canada from 1990 to 1997.

Values: the evidence collected was reviewed by the Medico-Legal Committee of the SOGC under the leadership of the primary author. The recommendations made were achieved by a committee consensus. These recommendations are practical and easy to implement.

Benefit, Harms and Costs: it is possible to minimize but not completely eliminate complications of laparoscopic surgery. Complications are reduced with increased operator expertise. A shortened hospital stay, rapid recovery from surgery, and a low overall complication rate are explicit with laparoscopy compared with laparotomy and were not measured.

Recommendations: there is fair (Class B) evidence to support the recommendations that appropriate patient selection, early recognition of complications, and full disclosure to patients

minimize the physical, emotional, and economic consequences of laparoscopic complications.

Validation: this committee opinion has been reviewed and approved by the Medico-Legal Committee, and the Executive Committee and Council of the Society of Obstetricians and Gynaecologists of Canada.

Sponsors: the Society of Obstetricians and Gynaecologists of Canada.

CLINICAL RISKS OF LAPAROSCOPY

GENERAL RISKS

Review of the recent literature highlighted several common and uncommon complications of laparoscopy. A sample reference list¹⁻¹⁰ describes the mechanisms, prevention, and management of these complications. It is important for the laparoscopist to understand possible complications and to have a fully informed discussion with the patient prior to surgery and after an adverse outcome, should one occur.

The minimal access and surgical skills of laparoscopy impose limitations of patient selection, surgical procedure, and surgeons. Obesity, previous bowel surgery, inflammatory bowel disease, peritonitis following previous surgery, and two prior midline incisions

may contribute to failure to achieve pneumoperitoneum and thus may contribute to bowel injury.⁶ Both patient and surgeon should be prepared for the procedure to proceed to convert to intraoperative laparotomy if there is a valid indication for the surgery. Open laparoscopy is not fail-safe in achieving successful pneumoperitoneum or in preventing laparoscopic complications.¹

There may be intrinsic complications from a surgical-related disease process, regardless of whether the procedure was performed by laparoscopy or laparotomy. Tubal interruptions fail, ectopic pregnancies rupture, and the occasional unexpected malignancy is encountered. Obtaining an informed consent should include a discussion of the biological consequences of potential disease processes as well of the potential problems associated with the technique of laparoscopy. Anaesthetic risks particular to laparoscopy result from operative pneumoperitoneum in the Trendelenburg position, which may pose ventilation-perfusion challenges. The surgeon's instruments and equipment are more complex during laparoscopy as compared to laparotomy, and therefore more prone to failure.

It is important that the public perception of minimal access surgery as 'simple surgery' be balanced with a full discussion of the attendant risks.

SPECIFIC INTRAOPERATIVE RISKS

In surgical practice, complications may arise intraoperatively, immediately post-operatively or much later. These complications may be related to anaesthesia, bleeding, infection or damage to structures adjacent to the surgical site. Laparoscopy is no exception. Some complications, however, are specific to laparoscopic surgery,^{1-4,6-8} including:

- malfunction of equipment
- trocar injuries
- endoscopic surgical instrument injuries
- thermal injuries
- subcutaneous emphysema

Immediate management of laparoscopic complications will help minimize sequelae.

Malfunctioning equipment requires immediate replacement, or abandonment of laparoscopy in favour of laparotomy or cancellation of surgery, depending on clinical circumstances. In a series of 2,324 laparoscopies, 20 complications were reported, 15 of which occurred with Verre's needle and trocar insertion.¹ A larger multicentre French study² of 29,966 laparoscopies also showed a high frequency of trocar injuries among the complications (total complication rate 4.64 per 1,000 laparoscopies). Since trocar injuries cause the most serious vascular and bowel complications,³ verification of correct placement of the Verre's needle cannot be overemphasized.

MEDICO-LEGAL RISKS

Data from 1990 to 1997 provided by the Canadian Medical Protective Association (CMPA) confirms that for gynaecologic laparoscopists, tubal occlusion is associated with the highest litigation rate when compared with all other surgical procedures performed.

Patients initiate legal action when there is a poor outcome, real or perceived, as a result of treatment. Clearly, a poor outcome does not always result from negligence or substandard care. It is equally certain that there are more poor outcomes

TABLE 1 ¹³ QUALITY OF EVIDENCE ASSESSMENT	CLASSIFICATION OF RECOMMENDATIONS
<p>The quality of evidence reported in these guidelines has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam.¹³</p> <p>I: Evidence obtained from at least one properly randomized controlled trial.</p> <p>II-1: Evidence from well-designed controlled trials without randomization.</p> <p>II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one centre or research group.</p> <p>II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940's) could also be included in this category.</p> <p>III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.</p>	<p>Recommendations included in these guidelines have been adapted from the ranking method described in the Classification of Recommendations found in the Report of the Canadian Task Force on the Periodic Health Exam.¹³</p> <p>A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.</p> <p>B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.</p> <p>C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds.</p> <p>D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination.</p> <p>E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.</p>

from laparoscopic surgery than the number resulting in lawsuits. Clinical risk management will reduce clinical risks and achieve better patient care.

RECOMMENDATIONS

The following recommendations to minimize operative laparoscopy risks result from current literature review and examination of the CMPA experience. The quality of evidence reported in these guidelines has been described using the evaluation of evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam (Table I).¹³

1. Select appropriate patients for laparoscopy: weight greater than 100 kg, previous bowel obstruction or peritonitis, inflammatory bowel disease or more than two previous sub-umbilical vertical incisions may pose greater risks than usual for laparoscopy. (II-3 B)
2. With all patients, discuss in simple language and document the risks, benefits, and alternatives to laparoscopy. (II-3 B)
3. For tubal occlusion discuss and document reversibility/irreversibility and failure. (II-3 B)
4. Consider conversion to laparotomy if difficulties are encountered, or abandon the procedure if no harm has been done and surgery is elective. (II-3 B)
5. Report technical difficulty in the operative record and discuss complications post-operatively with the patient. (II-3 B)
6. Consult an appropriate colleague if a complication occurs. This could be another gynaecologist, a general surgeon, a vascular surgeon or a urologist. (II-3 B)

J Soc Obstet Gynaecol Can 2000;22(11):974-6

REFERENCES

1. Bateman BG, Kolp LA, Hoeger K. Complications of laparoscopy: operative and diagnostic. *Fertil Steril* 1996;66:30-5.
2. Chapron C, Querleu D, Bruhat MA, et al. Surgical complications of diagnostic and operative gynaecologic laparoscopy. *Hum Reprod* 1998; 3(4):867-72.
3. Soderstrom RM. Injuries to major blood vessels during endoscopy. *J Amer Assoc of Gynaecol Lapar* 1997;4(3):395-8.
4. Kaali SG, Barad DH, Merkatz IR. Avoiding trocar injuries: is there a fail-safe method? *Fertil Steril* 1996;66(6): 1045-6.
5. Kruitwagen RD, Swinkels BM, Keyser KG, et al. Incidence and effect on survival of abdominal wall metastases at trocar or puncture sites following laparoscopy or paracentesis in women with ovarian cancer. *Gynaecol Oncol* 1996;60(2): 233-7.
6. Schrenk P, Woissetshlager R, Rieger R, Wayand W. Mechanism, management and prevention of laparoscopic bowel injuries. *Gastroint Endoscop* 1996;43(6):572-4.
7. Nordestgaard AG, Bodily KC, Osborne RW Jr, Buttorff JD. Major vascular injuries during laparoscopic procedures. *Amer J Surg* 1995;169(5):543-5.
8. Lewis JE. A simple technique for anticipating and managing secondary puncture site haemorrhage during laparoscopic surgery: a report of two cases. *J Reprod Med* 1995;40(10):729-30.
9. Kersten JR, Kane K, Coon R. Bronchospasm during pneumoperitoneum. *Anes Analg* 1995;81(5):1099-1101.
10. Hanney RM, Alle KM, Cregan PC. Major vascular injury and laparoscopy. *Aust NZ J Surg* 1995;65(7):533-5. (A review with 33 references)
11. Canadian Medical Protective Association: Information for the Society of Obstetricians and Gynaecologists of Canada. Medico-Legal Committee, August 1998.
12. Andrews LB, Stocking C, Krizek T, Gottlieb L. An alternative strategy for studying adverse effects in medical care. *Lancet* 1997;349:309-313.
13. Woolf SH, Battista RN, Angerson GM, Logan AG, EEL W. Canadian Task Force on the Periodic Health Exam. Ottawa. Canada Communication Group. 1994:xxxvii.